

REMARKS/ARGUMENT

Independent Claim 20 has been amended to specify that the particles comprise at least 10 wt% of a low-solubility drug. Support for this amendment is found in paragraph [0023] of the published application US 2007/0148232. Claim 20 has also been amended to specify that the particles comprise from 30 to 65 wt% of a poloxamer. Support for this amendment is found in the examples, where the amount of poloxamer in the particles ranges from 30 wt% (Examples 1 and 6) to 65 wt% (Example 7). Claim 20 has been further amended to specify that the particles comprise at least 5 wt% of a stabilizing polymer. Support for this amendment is found in paragraph [0026] of the published application. Claim 20 has been further amended to recite that the particles are in the form of a solid solution of the low-solubility drug homogeneously distributed throughout the poloxamer and the stabilizing polymer. Support for this amendment is found in paragraph [0027] in the published application. Finally, claim 20 has been amended to specify that the composition provides improved physical stability relative to a specific control. Support for this amendment is found in paragraph [0075] of the published application.

Claims 20-29 and 31-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld et al. WO 02/089835 (Infeld) in view of Babcock et al. EP1027886 (Babcock). Claim 21 has been cancelled, rendering this rejection moot. This rejection is otherwise traversed for the following reasons.

Infeld discloses a solid unit oral pharmaceutical dosage form of amorphous nelfinavir mesylate and a poloxamer. Abstract. The solid dosage form is produced by a hot melt granulation process comprising blending the nelfinavir mesylate and the copolymer, and heating the blend to a temperature less than the decomposition temperature of the drug. This process results in granules of the drug embedded in the poloxamer. Page 6, lines 8-14. Other excipients can be included in the melt granulation. Page 6, lines 20-21.

The Examiner concedes that Infeld does not disclose the inclusion of a stabilizing polymer such as HPMCAS in the granules, but contends that Babcock provides this missing disclosure. The examiner is mistaken, inasmuch as the only reference to HPMCAS by Babcock is as a polymer that is stated to be "not within the scope of the invention." Babcock [0058]. Without more, this obviousness rejection is without merit.

Claims 20-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Beyerinck et al. US 2003/0163931 (Beyerinck). Claim 21 has been cancelled, rendering its rejection moot. This rejection is otherwise traversed for the following reasons.

The Examiner points to claim 19 of Beyerinck, stating that the particles produced by the Beyerinck process may have a blend of polymers, such as HPMCAS and a poloxamer. However, there is no disclosure of the relative amounts of drug, HPMCAS or poloxamer in the Beyerinck compositions, nor formation of particles consisting of a solid solution of the drug homogeneously distributed throughout the poloxamer and stabilizing polymer, all as claimed in independent claim 20. In addition, there is no disclosure of the relative degree of improvement in physical stability provided by the compositions, also as claimed in claim 20 as amended. Accordingly, claim 20 and those claims dependent therefrom (claims 22-34) are not rendered obvious by Beyerinck.

Though not so stated in the Office Action, the Examiner appears to rely on Infeld for this rejection, contending that it would have been obvious for one of ordinary skill to modify the composition of Beyerinck by adding a poloxamer as taught by Infeld.

However, Infeld does not disclose the relative amounts of drug, poloxamer, and stabilizing polymer in the composition, nor that the particles consist of a solid solution of drug homogeneously distributed throughout poloxamer and stabilizing polymer, as claimed in independent claim 20. Since claims 22-34 all ultimately depend from claim 20, they are likewise not rendered obvious by the combination of Beyerinck and Infeld.

Early and favorable reconsideration is respectfully solicited.

Respectfully submitted,

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